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EXAMINER

KOPCHIK, STEPHEN W

ART UNIT	PAPER NUMBER
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2624

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02/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,479	Applicant(s) ECK ET AL.	
	Examiner STEPHEN KOPCHIK	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

1. Examiner withdraws his objections to the Claims and the drawings as the Applicant has complied with his earlier suggestions.
2. Examiner withdraws his provisional double-patenting rejection because the Applicant correctly points out the '006 Application is not prior art.
3. Regarding Claims 1, 12, and 13, Applicant alleges that Packer does not disclose "the estimated position of the object in the map image being brought into register...only a section of the map image being used" as recited in the amended claims. The Examiner respectfully disagrees.

Packer discloses the use of a stored high resolution cardiac image which can be reasonably interpreted as a "map image" as claimed (Col.9, Lines 37-53). Further, Packer discloses a current image is registered against the stored high resolution cardiac image to create a registered high resolution image of the heart wall (Col. 9, Lines 53-67 and Col.10, Lines 1-22); this can be reasonably interpreted to encompass "current image" as used in the claim language. Packer then discloses the

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location of the medical device is output to the display to overlay the anatomical image... the medical device overlay can be an image of the device, an icon that represents the device, or simple a cursor or cross-hairs (Col.10, Lines 31-36). Taking the broadest reasonable interpretation of the prior art disclosure, "anatomical image" is not explicitly defined and one of ordinary skill in the art would take it to mean either the high resolution cardiac image (i.e. map image) or the registered high resolution image of the heart wall (i.e. current image). Thus, Packer discloses that it is estimating the position of the object with in image, either map image or current image, through the use of a image or icon of the object, or cursor.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows (see also MPEP 2106):

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes

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but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

4. Claims 1-3 9-10, 16, and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 1-3, 9-10, 13, 16, and 18-19 define a "device". However, while the preamble defines a "device", which would typically be indicative of an "apparatus", the body of the claim lacks definite structure indicative of a physical apparatus. Therefore, the claim as a whole appears to be nothing more than a "device" of software elements, thus defining functional descriptive material per se.

Functional descriptive material may be statutory if it resides on a "computer-readable medium or computer-readable memory". The claim(s) indicated above lack structure, and do not define a computer readable medium and are thus non-statutory for that reason (i.e., "When functional descriptive material is

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recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" - Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests:

1. Amending the claim(s) to embody the program on "computer-readable medium" or equivalent; assuming the specification does NOT define the computer readable medium as a "signal", "carrier wave", or "transmission medium" which are deemed non-statutory; or

2. Adding structure to the body of the claim that would clearly define a statutory apparatus.

Any amendment to the claim should be commensurate with its corresponding disclosure.

5. Claims 13 and 19 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent¹ and recent Federal Circuit

¹ *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

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decisions² indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. For example, Claim 13 contains language of such breadth that it can be reasonably interpreted to be wholly implemented by pure software alone, i.e. functional descriptive material. Further, there is no transformation of the underlying subject matter because there is no claimed depiction of the modified data or signal as an external representation of the physical object or substance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

² *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19 rejected under 35 U.S.C. 102(b) as being anticipated by Packer.

3. (Currently Amended) Regarding Claim 1, Packer discloses a device for combining a current image ~~(A)~~ of an object ~~(8)~~ (Col.8, Lines 47-50 and Col.9 21-24) and a map image ~~(B)~~ of the dwell region ~~(9)~~ of the object ~~(8)~~ (Col.9, Lines 37-52), containing a data-processing system ~~(5)~~ that is arranged

a) to estimate the position of the object ~~(8)~~ in relation to the map image (Col.9, Lines 59-67 and Col.10, Lines 1-5), and

b) to combine the map image ~~(B)~~ around the estimated position of the object ~~(8)~~ with the current image ~~(A)~~, the estimated position of the object in the map image ~~(B)~~ being brought into register with the actual position of the object in the current image ~~(A)~~, ~~and only a section (7) of the map image (B) and/or of the current image (A) being used~~ (Col.10, Lines 31-36).

4. Claims 2-6, 8-11, and 18 depend upon Claim 1, therefore the rejection of Claim 1 is incorporated into the rejections of

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Claims 2-6, 8-11, and 18 and only further limitations will be addressed below.

5. (Currently Amended) Regarding Claim 2, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein the object ~~(8)~~ is located in a path network ~~(9)~~ and the map image ~~(B)~~ at least partially reproduces the path network ~~(9)~~ (Col.8, Lines 47-50 and Col.9, Lines 42-44; taking the broadest reasonable interpretation of the claim language, the examiner interprets "path network" to include a vascular system, which the prior art discloses the use of a flexible catheter in a vascular system and corresponding stored images of the vascular system).

6. (Currently Amended) Regarding Claim 3, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein the map image ~~(B)~~ contains additional information about the structures ~~and/or~~ or functions of the dwell region ~~(9)~~ of the object ~~(8)~~ (Col.9, Lines 42-44; the prior art discloses stored images of the vascular system at successive positions during the cardiac cycle, it is inherent that each of these positions would contain additional information, beyond just a mapping, about the structures and/or functions of the vascular system at the

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specific heart cycle that make it different from the other cycles).

7. (Currently Amended) Regarding Claim 4, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein it contains a monitor (10) for displaying the combination of the current image ~~(A)~~ and the section ~~(7)~~ of the map image ~~(B)~~ (Col.10, Lines 31-36 and Lines 48-53).

8. (Currently Amended) Regarding Claim 5, Packer discloses a device as claimed in claim 1, ~~characterized in that it has~~ comprising a memory ~~(6)~~ for storing a number of map images ~~(B)~~, which are being categorized according to a varying state of the dwell region ~~(9)~~ of the object ~~(8)~~ (Col.9, Lines 42-52).

9. Claim 7 depends upon Claim 5, therefore the rejection of Claim 5 is incorporated into the rejection of Claim 7 and only further limitations will be addressed below.

10. (Currently Amended) Regarding Claim 6, Packer discloses a device as claimed in claim 1, ~~characterized in that it has~~ comprising a sensor device ~~(3)~~ for detecting at least one parameter that describes a varying state of the dwell region of

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the object ~~(8)~~, preferably for detecting an electrocardiogram and/or the respiratory cycle (Col.9, Lines 5-23).

11. Claim 14 depends upon Claim 6, therefore the rejection of Claim 6 is incorporated into the rejection of Claim 14 and only further limitations will be addressed below.

12. (Currently Amended) Regarding Claim 7, a device as claimed in claim 5, ~~characterized in that~~ wherein the data-processing system ~~(5)~~ is arranged to select from the memory ~~(6)~~ a map image ~~(B)~~ whose associated state of the dwell region ~~(9)~~ of the object ~~(8)~~ is a best possible match for the state of the dwell region during the current image ~~(A)~~ (Col.9, Lines 59-67 and Col.10, Lines 1-5).

13. (Currently Amended) Regarding Claim 8, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein the data-processing system ~~(5)~~ is arranged to assign in the map image ~~(B)~~ to each pixel a probability that it belongs to a spatially-defined structure, ~~such as a path network (9) for example~~ (Col.9, Lines 59-67 and Col.10, Lines 1-5).

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14. Claim 15 depends upon Claim 8, therefore the rejection of Claim 8 is incorporated into the rejection of Claim 15 and only further limitations will be addressed below.

15. (Currently Amended) Regarding Claim 9, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein the data-processing system ~~(5)~~ is arranged to produce a distance image ~~(D)~~ from the map image ~~(B)~~ by a distance transformation (Col.9, Lines 53-67 and Col.10, Lines 1-8; taking the broadest reasonable interpretation of the above claim, the distance image can be interpreted as being a type of function that outputs the likelihood of registration between the map image and the object image. Further, the applicants own specification suggests the distance image is only used for estimating the position of the object in relation to the map image and is never displayed (Page 6, Lines 21-23). This suggests the distance image does not have to be an actual 'image' but only an estimation tool. Therefore, the prior art anticipates the distance image as claimed herein by calculating a cost function in matching the stored map image to the object image when registering).

16. (Currently Amended) Regarding Claim 10, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein, in

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the section ~~(7)~~ of the map image being used, points not belonging to a spatially-defined structure, ~~such as a path network (9) for example,~~ are transparent (Col.10, Lines 48-67 and Col.11, Lines 1-13; The prior art discloses different embodiments on how the display is viewed by the physician, including being able to focus on a specific region of the anatomy, therefore it is inherent that the display device in the prior art would allow non-matching points to be transparent in order to better view the targeted portion).

17. Claim 16 depends upon Claim 10, therefore the rejection of Claim 10 is incorporated into the rejection of Claim 16 and only further limitations will be addressed below.

18. (Currently Amended) Regarding Claim 11, Packer discloses a device as claimed in claim 1, ~~characterized in that~~ wherein it has an imaging means, ~~especially an X-ray apparatus (4) and/or an NMR apparatus,~~ for producing the current image ~~(A) and optionally the map image (B)~~ (Col.10, Lines 31-36 and 48-52).

19. Claim 17 depends upon Claim 11, therefore the rejection of Claim 11 is incorporated into the rejection of Claim 17 and only further limitations will be addressed below.

20. (Currently Amended) Regarding Claim 12, Packer discloses a device for combined portrayal of a current image ~~(A)~~ of an object ~~(8)~~ that is located in a path network ~~(9)~~ (Col.8, Lines 47-50 and Col.9 21-24) and a map image ~~(B)~~ of the path network ~~(9)~~ (Col.9, Lines 37-52) containing a data-processing system ~~(5)~~ that is arranged

a) in the map image ~~(B)~~, to assign to each pixel a probability that it belongs to the path network ~~(9)~~ (Col.9, Lines 59-67 and Col.10, Lines 1-5);

b) to produce a distance image ~~(D)~~ from the map image ~~(B)~~ by a distance transformation (Col.9, Lines 53-67 and Col.10, Lines 1-8; taking the broadest reasonable interpretation of the above claim, the distance image can be interpreted as being a type of function that outputs the likelihood of registration between the map image and the object image. Further, the applicants own specification suggests the distance image is only used for estimating the position of the object in relation to the map image and is never displayed (Page 6, Lines 21-23). This suggests the distance image does not have to be an actual 'image' but only an estimation tool. Therefore, the prior art anticipates the distance image as claimed herein by calculating

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a cost function in matching the stored map image to the object image when registering).

c) by means of the distance image, ~~(D)~~ to estimate the position of the object ~~(8)~~ in relation to the map image ~~(B)~~ of the path network ~~(9)~~ (Col.9, Lines 53-67 and Col.10, Lines 1-8), and

d) to superimpose the map image, ~~(B)~~ wholly or in sections on the current image ~~(A)~~ or a section thereof so that the estimated position of the object in the map image ~~(B)~~ is brought into register with the actual position of the object in the current image ~~(A)~~, only a section of the map image is used (Col.10, Lines 31-36).

21. (Currently Amended) Regarding Claim 13, Claim 13 is a method claim corresponding to apparatus Claim 1, therefore Claim 13 has been analyzed and rejected with respect to Claim 1.

22. (New) Regarding Claim 14, Packer discloses a device as claimed in claim 6, wherein the varying state comprises an electrocardiogram or respiratory cycle (Col.9 Lines 5-23).

23. (New) Regarding Claim 15, Packer discloses a device as claimed in claim 8, wherein the spatially-defined structure

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comprises a path network (Col.9, Lines 59-67 and Col.10, Lines 1-5).

24. (New) Regarding Claim 16, Packer discloses a device as claimed in claim 10, wherein the spatially-defined structure comprises a path network (Col.9, Lines 59-67 and Col.10, Lines 1-5).

25. (New) Regarding Claim 17, packer discloses a device as claimed in Claim 11, wherein the imaging means comprise an X-ray apparatus or an NMR apparatus (Col.10, Lines 31-36 and 48-52).

26. (New) Regarding Claim 18, Packer discloses a device as claimed in claim 1, wherein only a section of the current image is used (Col.10, Lines 31-36).

27. (New) Regarding Claim 19, Claim 19 is a method claim corresponding to apparatus Claim 18, therefore Claim 19 has been analyzed and rejected with respect to Claim 18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN

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KOPCHIK whose telephone number is (571)270-7117. The examiner can normally be reached on Monday -Thursday 9:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on (571)272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/STEPHEN KOPCHIK/
Examiner, Art Unit 2624

/Vikkram Bali/

Supervisory Patent Examiner, Art Unit 2624